

**IN THE CLAIMS:**

Please cancel claims 1-21 without prejudice.

Please amend claims 40 and 42 and add new claim 83 as shown below:

22. (Original) Crystalline carvedilol hydrate.
23. (Original) Crystalline carvedilol.
24. (Original) Crystalline carvedilol (methyl-ethyl-ketone) solvate.
25. (Original) Crystalline carvedilol Form III.
26. (Original) The crystalline carvedilol of claim 25, characterized by an X-ray powder diffraction pattern having peaks at about  $8.4 \pm 0.2$ ,  $17.4 \pm 0.2$ , and  $22.0 \pm 0.2$  degrees two-theta.
27. (Original) The carvedilol of claim 26, further characterized by an X-ray powder diffraction pattern having peaks at about  $9.3 \pm 0.2$ ,  $11.6 \pm 0.2$ ,  $13.2 \pm 0.2$ ,  $13.5 \pm 0.2$ ,  $14.2 \pm 0.2$ ,  $15.3 \pm 0.2$ ,  $15.8 \pm 0.2$ ,  $18.4 \pm 0.2$ ,  $19.4 \pm 0.2$ ,  $20.6 \pm 0.2$ ,  $21.4 \pm 0.2$ ,  $26.5 \pm 0.2$  and  $27.6 \pm 0.2$  degrees two-theta.
28. (Original) The crystalline carvedilol of claim 24, characterized by a water content of about 2.0 % by weight.
29. (Original) A pharmaceutical composition comprising a therapeutically effective amount of the crystalline carvedilol of claim 24, and a pharmaceutically acceptable carrier.
30. (Original) A method for treating a patient suffering from congestive heart failure by administering a therapeutically effective amount of crystalline carvedilol Form III.
31. (Original) A method for treating a patient suffering from hypertension by

- administering a therapeutically effective amount of crystalline carvedilol Form III.
32. (Original) Crystalline carvedilol Form IV.
  33. (Original) The crystalline carvedilol of claim 32, characterized by an X-ray powder diffraction pattern having peaks at about  $11.9 \pm 0.2$ ,  $14.2 \pm 0.2$ ,  $18.3 \pm 0.2$ ,  $19.2 \pm 0.2$ ,  $21.7 \pm 0.2$ , and  $24.2 \pm 0.2$  degrees two-theta.
  34. (Original) The crystalline carvedilol of claim 33, further characterized by an X-ray powder diffraction pattern having peaks at about  $15.7 \pm 0.2$ ,  $16.5 \pm 0.2$ ,  $17.7 \pm 0.2$ ,  $19.6 \pm 0.2$ ,  $22.2 \pm 0.2$ ,  $23.9 \pm 0.2$ ,  $24.9 \pm 0.2$ ,  $27.4 \pm 0.2$  and  $28.2 \pm 0.2$  degrees two-theta.
  35. (Original) Crystalline carvedilol (methyl-ethyl-ketone) solvate Form V.
  36. (Original) The crystalline carvedilol of claim 35, characterized by an X-ray powder diffraction pattern having peaks at about  $4.1 \pm 0.2$ ,  $10.3 \pm 0.2$ , and  $10.7 \pm 0.2$  degrees two-theta.
  37. (Original) The crystalline carvedilol of claim 36, further characterized by an X-ray powder diffraction pattern having peaks at about  $11.5 \pm 0.2$ ,  $12.6 \pm 0.2$ ,  $14.0 \pm 0.2$ ,  $14.8 \pm 0.2$ ,  $15.4 \pm 0.2$ ,  $16.4 \pm 0.2$ ,  $16.8 \pm 0.2$ ,  $18.8 \pm 0.2$ ,  $20.8 \pm 0.2$ ,  $21.1 \pm 0.2$ ,  $21.6 \pm 0.2$ , and  $25.4 \pm 0.2$  degrees two-theta.
  38. (Original) The crystalline carvedilol of claim 35, characterized by a methyl-ethyl-ketone content of about 14 % by weight.
  39. (Original) Carvedilol HCl Hydrate.
  40. (Currently amended) The crystalline carvedilol of claim [39,] 83 characterized by an X-ray powder diffraction pattern having peaks at about  $6.5 \pm 0.2$ ,  $10.2 \pm 0.2$ ,  $10.4 \pm$

0.2,  $15.8 \pm 0.2$ ,  $16.4 \pm 0.2$  and  $22.2 \pm 0.2$  degrees two-theta.

41. (Original) The crystalline carvedilol of claim 40, further characterized by an X-ray powder diffraction pattern having peaks at about  $14.2 \pm 0.2$ ,  $14.7 \pm 0.2$ ,  $16.4 \pm 0.2$ ,  $17.7 \pm 0.2$ ,  $20.0 \pm 0.2$ ,  $21.5 \pm 0.2$ ,  $21.9 \pm 0.2$ ,  $22.9 \pm 0.2$ ,  $25.2 \pm 0.2$ ,  $25.3 \pm 0.2$ ,  $27.2 \pm 0.2$ ,  $27.4 \pm 0.2$ ,  $28.2 \pm 0.2$ ,  $28.6 \pm 0.2$ ,  $29.6 \pm 0.2$  degrees two theta.
42. (Currently amended) The crystalline carvedilol of claim [39,] 83 characterized by a water content of about 3.5% by weight.
43. (Original) A method for preparing crystalline carvedilol Form I, comprising the steps of:
- a) dissolving carvedilol in a solution by heating;
  - b) heating the solution until the crystalline carvedilol is completely dissolved;
  - c) reducing the temperature of the solution;
  - d) agitating the solution for a period of time;
  - d) further reducing the temperature of the solution;
  - e) further agitating the solution for a period of time; and,
  - e) collecting crystalline carvedilol Form I.
44. (Original) The method of claim 43, wherein the dissolving step is performed by heating the solution to about 77°C.
45. (Original) The method of claim 43, wherein the step of reducing the temperature of the solution is performed by cooling the solution to about 50° C in a time period of about 15 min.
46. (Original) The method of claim 43, wherein the step of agitating the solution is

performed at about 50° C for about 48 hours.

47. (Original) The method of claim 43, wherein the step of further reducing the temperature of the solution is performed by cooling the solution to about 10°C in about 0.75 hours with agitation.
48. (Original) The method of claim 43, wherein the step of further agitating the solution is performed by stirring the suspension for more than about 5 hours.
49. (Original) A method for preparing crystalline carvedilol Form II, comprising the steps of:
  - a) forming a solution of carvedilol by dissolving carvedilol in a solvent;
  - b) precipitating carvedilol Form II by cooling the solution; and,
  - c) isolating crystalline carvedilol Form II.
50. (Original) The process of claim 49, wherein the temperature is from about 40° C to about the boiling temp of the solvent.
51. (Original) The process of claim 49, wherein the precipitated carvedilol Form II is isolated by filtration
52. (Original) The process of claim 49, wherein the solution is cooled to a temperature from about -20°C to ambient temperature.
53. (Original) The process of claim 49, wherein the solvent is selected from the group consisting of methanol, ethanol, 1-propanol, isopropanol, n-butanol, ethylene glycol, butyl acetate, isobutyl methyl ketone, dichloromethane, dichloroethane, acetonitrile, acetone, isoamylalcohol, xylene and toluene.
54. (Original) A method for preparing crystalline carvedilol Form II, comprising the steps

of:

- a) forming a solution of carvedilol by dissolving carvedilol in a solvent mixture;
  - b) precipitating carvedilol Form II by cooling the solution to about -20°C; and,
  - c) isolating crystalline carvedilol Form II.
55. (Original) The process of claim 54, wherein the temperature of the solution is from about 40°C to about the boiling temperature of the solvent.
56. (Original) The process of claim 54, wherein the precipitated carvedilol Form II is isolated by filtration.
57. (Original) The process of claim 54, wherein the solution is cooled to a temperature from about -20°C to ambient temperature.
58. (Original) The method of claim 54, wherein the solvent mixture is selected from the group consisting of acetone: cyclohexane, chloroform: cyclohexane, dichloroethane: cyclohexane, dichloromethane: cyclohexane, pyridine: cyclohexane, tetrahydrofuran: cyclohexane, dioxane: cyclohexane, acetone: hexane, chloroform: hexane, dichloroethane: hexane, dichloromethane: hexane, tetrahydrofuran: hexane and ethanol: hexane.
59. (Original) A method for preparing crystalline carvedilol Form III, comprising the steps of:
- a) dissolving carvedilol in a solvent to form a solvent solution; and,
  - b) precipitating crystalline carvedilol Form III from the solvent solution using water as an anti-solvent.
60. (Original) The method of claim 59, wherein water is present in the solvent solution

during the dissolving step.

61. (Original) The method of claim 59, wherein the precipitation step is performed by adding water to the solution after carvedilol is fully dissolved in the solvent.
62. (Original) The method of claim 59, wherein the dissolving step is performed at elevated temperature.
63. (Original) The method of claim 59, wherein the elevated temperature is from about 40° C to about 90° C.
64. (Original) The method of claim 59, wherein the elevated temperature is about 55 °C.
65. (Original) The method of claim 59, wherein the dissolving step is performed at ambient temperature.
66. (Original) The method of claim 59, wherein the solvent is selected from the group consisting of pyridine, dioxane, methanol, ethanol, isopropanol and chloroform.
67. (Original) The method of claim 59, wherein the solvent consists of a mixture of solvents.
68. (Original) A method for preparing crystalline carvedilol Form IV, comprising the steps of:
  - a) dissolving carvedilol in a solvent to form a solvent solution;
  - b) adding an anti-solvent to the solvent solution; and,
  - c) precipitating crystalline carvedilol Form IV from the solvent solution.
69. (Original) The method of claim 68, wherein the solvent is methyl ethyl ketone.
70. The method of claim 68, wherein the anti-solvent is cyclohexane.
71. (Original) The method of claim 68, wherein the dissolving step is performed at from

about 10°C to about 50 °C.

- 72. (Original) The method of claim 68, wherein the dissolving step is performed at about 55 °C.
- 73. (Original) The method of claim 68, wherein the dissolving step is performed at ambient temperature.
- 74. (Original) A method for preparing crystalline carvedilol Form V, comprising the steps of:
  - a) dissolving carvedilol in a solvent to form a solvent solution; and,
  - b) precipitating and isolating crystalline carvedilol Form V from the solvent solution.
- 75. (Original) The method of claim 74, wherein the solvent is methyl ethyl ketone.
- 76. (Original) The method of claim 74, wherein the dissolving step is performed by dissolving carvedilol at ambient temperature.
- 77. (Original) The method of claim 74, wherein the temperature of dissolution is from about 10° C to about 80° C.
- 78. (Original) The process of claim 74, wherein carvedilol Form V is precipitated by cooling.
- 79. (Original) A method for preparing crystalline carvedilol Form V, comprising the steps of:
  - a) dissolving carvedilol in a solvent to form a solvent solution; and,
  - b) precipitating and isolating crystalline carvedilol Form V from the solvent solution

wherein the precipitation step is performed by adding an anti-solvent.

- 80. (Original) The method of claim 79, wherein the solvent is methyl ethyl ketone.
- 81. (Original) The method of claim 79, wherein the dissolving step is performed by dissolving carvedilol at ambient temperature.
- 82. (Original) The method of claim 79, wherein the of anti-solvent is hexane.

The claims have been amended as follows:

- 83. (New) The carvedilol of claim 39 wherein the carvedilol HCl hydrate is crystalline.